

Applicants: Maureen J. Charron and Ellen B. Katz  
Serial No.: 09/886,954  
Filed: June 21, 2001  
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#### REMARKS

Claims 1, 4-11, and 14-20 were pending in the subject application. By this Amendment, applicants have canceled claims 4, 5, 14 and 15 without prejudice or disclaimer and have amended claims 1, 6, 11 and 16. Accordingly, upon entry of this Amendment, claims 1, 6-11, and 16-20 will be pending and under examination.

Applicants maintain that the amendments to the claims do not raise an issue of new matter. Support for the amendments to claims 1 and 11 can be found at least in the previous version of the claims. Support for the amendments to claims 6 and 16 can be found at least in the previous version of the claims and in original claims 4 and 14. Accordingly, entry of the amendments is respectfully requested.

#### Scope of Amended Claims

Independent Claims 1 and 11 have been amended to be commensurate with the scope of the invention. Applicants' invention is directed to a method of determining whether a subject has a mammary adenocarcinoma or an endometrial adenocarcinoma by detecting *elevated* GLUTx expression (Claim 1) and to a method for assessing the efficacy of therapy to treat mammary adenocarcinoma or endometrial adenocarcinoma comprising assaying for GLUTx expression where *elevated* GLUTx expression is indicative of a need to continue therapy (Claim 11). The claims include the active step of "assaying a diagnostic sample of the subject for GLUTx expression..." Methods for detecting GLUTx expression using an antibody or nucleic acid probe are recited in dependent claims.

#### Rejections under 35 U.S.C. §112, Second Paragraph

The claims are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the term "hybridizes."

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Applicants respectfully traverse this rejection.

As indicated above, independent claims 1 and 11 have been amended to be commensurate with the scope of the invention and no longer recite the term "hybridizes." Only claims 8 and 18, which depend from and further limit claims 1 and 11, respectively, now recite "hybridizes." As set forth in more detail in the section below, one of ordinary skill in the art would know the hybridization conditions required to detect expression of a specific nucleic acid such as that encoding GLUTx protein. Applicants maintain that one of ordinary skill in the art would understand the metes and bounds of the invention as set forth in the claims. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

#### Rejections under 35 U.S.C. §112, First Paragraph

The claims are rejected under the written description requirement of 35 U.S.C. §112, first paragraph, as regards the full breadth of the claims.

Applicants respectfully traverse this rejection.

Applicants note that the amended claims no longer recite the term "agent."

In regard to the inventors being in possession of using a nucleic acid probe to detect GLUTx expression, the Examiner is first referred to priority document U.S. Patent Application No. 09/516,493, filed March 1, 2000, which as indicated in the first paragraph of the subject specification, was expressly incorporated by reference when the subject application was filed. A copy of U.S. Patent Application No. 09/516,493 as filed on March 1, 2000 is attached hereto as **Exhibit 1**. In the priority document, nucleic acid probes to GLUTx are discussed at least on page 8, line 27 through page 9, line 14; and page 15, lines 6-26. High and moderate stringency conditions are set forth on page 8, lines 27-30. Northern blot analysis of GLUTx expression is described at least on page 5, lines 15-21; page 20, lines 11-18; page 22, lines 23-28; and page 39, lines 12-30; and

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illustrated in Figures 1-2. In situ hybridization studies of GLUTx expression are described on page 38, lines 23-27.

Furthermore, applicants note that it was standard for one of ordinary skill in the art at the time of the subject invention to detect expression of a nucleic acid using a probe that hybridizes to the nucleic acid sequence. Examples can be found for GLUTx in documents already of record, see e.g.: (1) Doege et al., J Biol Chem 275: 16275-80, 2000; (2) Ibberson et al., J Biol Chem 275: 4607-12, 2000; (3) Reagan et al., PNAS 98: 2820-5, 2001; and (4) WO 99/18125.

Applicants maintain that the invention is described in the specification in such a way as to convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

#### Rejections under 35 U.S.C. §102(a)

Claims 1 and 4-7 are rejected under 35 U.S.C. §102(a) as anticipated by Goldman et al., Abstract #5033, Proc. Am. Assoc. Cancer Res. 42: 937, March, 2001.

Applicants respectfully traverse this rejection.

The cited Abstract is a preliminary communication of a portion of the claimed invention, which was invented by Maureen J. Charron and Ellen B. Katz. Applicants attach hereto as **Exhibit 2** a Declaration of Drs. Maureen J. Charron and Ellen B. Katz under 37 C.F.R. §1.132. In the attached Declaration, Drs. Charron and Katz state that none of the other persons named as coauthors on the Abstract made a conceptual contribution to the invention claimed in the subject application. The Declaration also sets forth the contribution of the other coauthors on the Abstract. Therefore, the cited Abstract does not describe the claimed invention before the invention was invented by Maureen J. Charron and Ellen B. Katz. Accordingly, the cited Abstract does not

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anticipate the claimed invention (MPEP §2132.01), and reconsideration and withdrawal of this ground of rejection are respectfully requested.

Supplemental Information Disclosure Statement

Applicants are submitting the present Information Disclosure Statement to supplement the Information Disclosure Statements filed on November 1, 2002 and April 1, 2003 in connection with the subject application.

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the three references which are both listed on the attached form PTO/SB/08A (1 page) (**Exhibit 3**) and attached hereto (**Exhibit 4**).

Applicants are submitting the subject Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2) before the mailing of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application. A check for \$180.00 is enclosed to cover the fee set forth in 37 C.F.R. §1.17(p) for submitting an Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2).

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CONCLUSIONS

In view of the amendments and remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the October 5, 2004 Office Action and earnestly solicit allowance of the claims under examination, namely claims 1, 6-11, and 16-20.

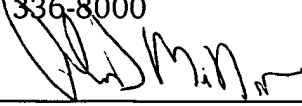
If there are any minor matters that prevent allowance of the subject application, applicants request that the Examiner telephone the attorney indicated below.

No fee, other than the enclosed \$180.00 fee for submitting an Information Disclosure Statement, is deemed necessary in connection with the filing of this response. However, if any other fee is required to preserve the pending of the subject application, authorization is hereby given to charge any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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Dated: December 13, 2004  
New York, New York

By   
Alan D. Miller, Reg. No. 42,889